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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,506	06/27/2003	Scott Alexander Beaudry	J&J-5048	9281

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EXAMINER

CRAIG, PAULA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,506	BEAUDRY, SCOTT ALEXANDER	
	Examiner	Art Unit	
	Paula L. Craig	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. Figs. 1-6 are objected to under 37 CFR 1.84 or 1.152 for the reasons indicated on the enclosed PTO-948 form. Corrected drawings are required.

Claim Objections

2. Claims 1-15 are objected to because of the following informalities: Claims 1 and 15 contain the misspelled terms "hemstatic", "hemstasis" and "hemostic". These terms have been interpreted by the Examiner as "hemostatic", "hemostasis" and "hemostatic" respectively. In addition, the phrase "in fluid communication said cleansing element" in lines 9-10 of Claim 1 is considered to mean "in fluid communication with said cleansing element". Claims 2-14 are objected to as being dependent on Claim 1.
3. Claim 14 is considered by the Examiner to be a substantial duplicate of Claim 5. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 4, 7, and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 3 includes the limitation "said frangible seal is located substantially at the distal end of said stick" while Claim 4 includes the limitation "said frangible seal is located downwardly from the distal end of said stick". Both Claim 3 and Claim 4 are dependent on Claim 2. The difference between "located substantially at the distal end" and "located downwardly from the distal end" is not clear to the Examiner. For purposes of this examination, the Examiner interprets both these limitations to mean that the frangible seal is located in the vicinity of the distal end.

7. Claims 7 and 10 recite the limitation "said hemostat-containing element" in line 1. There is insufficient antecedent basis for this limitation in the claims. Claim 13 recites the limitation "the hemostat-containing element". For purposes of this examination, the Examiner considers these phrases to refer to the hemostatic element, in lines 5-6 of Claim 1.

8. Claim 10 recites the limitation "the hemostat" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 11-13 are rejected as being dependent on Claim 10.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 5, 6, 10, 13, and 14, as best understood by the Examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,324,855 to Heimlich. For Claim 1, Applicant's preamble term "swab" is considered as a limitation by the Examiner, in that it gives life and meaning to the claim. See *Kropa v. Robie*, 187F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Heimlich discloses a swab (see Figs. 1 and 4 and col. 2, lines 65-68). Heimlich teaches the swab having a stick (reference number 10 of Figs. 1 and 4, and col. 2, line 66) and a wound treating element (reference number 18 of Figs. 1 and 4, and col. 3, lines 24-30). The stick has a proximal portion, a proximal end, a distal portion, and a distal end (see Fig. 4). The stick has a reservoir for containing a liquid (reference number 52 of Fig. 4, and col. 6, lines 3-8). The wound treating element is secured to the distal portion (see Fig. 4). The wound treating element includes a cleansing element, which is also a hemostatic element for effecting hemostasis of a wound (reference number 18 of Fig. 4). The swab of Heimlich is capable of cleansing a wound. The word "hemostasis" is interpreted by the Examiner to mean any stoppage of bleeding. The swab may be made of gauze (see Heimlich, col. 3, lines 24-33). Gauze is known for a hemostatic effect when used in bandages and the like, and the swab of Heimlich is capable of performing this function. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See *Ex parte Masham*, 2 USPQ2d 1647

(Bd. Pat. App. & Inter. 1987), *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967), and *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Note that Claim 1 does not require that the cleansing element and the hemostatic element be discrete. The reservoir is in fluid communication with the cleansing element (Fig. 4 and col. 6, lines 12-16).

11. For Claims 5 and 6, Heimlich teaches the reservoir containing an antiseptic or cleansing solution (see col. 5, lines 42-45).

12. For Claim 10, Heimlich discloses the hemostat as fibers, in the form of gauze. (See col. 3, lines 26-32.)

13. For Claim 13, which is dependent on Claim 10, Heimlich discloses a cleansing element and hemostatic element placed opposite each other on either side of the stick (the two sides of the sponge portion 18 of Heimlich, Figs. 1-6 and 16-18, and col. 3, lines 24-46, and col. 5, lines 3-9). Heimlich teaches a liquid impermeable film placed between the cleansing element and the hemostatic element (see reference number 44 of Fig. 18, and col. 4, lines 51-61).

14. For Claim 14, Heimlich discloses the reservoir containing a liquid (see col. 5, lines 52-55). The swab of Heimlich is capable of applying a liquid to a wound.

15. Claims 1-4, as best understood by the Examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,100,028 to Seifert.

16. For Claim 1, Seifert discloses a swab having a stick and a wound treating element (reference numbers 28, 30, and 32 of Fig. 3, and col. 4, lines 50-57). The stick has a proximal portion, a proximal end, a distal portion, and a distal end (see Fig. 3).

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The stick has a reservoir for containing a liquid (see Figs. 1 and 3, reference number 12, and col. 3, lines 5-12 and 38-42, and col. 4, lines 59-61). The wound treating element is secured to the distal portion (see Fig. 3). The wound treating element includes a cleansing element, which is also a hemostatic element (reference number 32 of Fig. 3). The cleansing element may be made of cotton or similar saturable material (see col. 4, lines 50-55). Cotton has a hemostatic effect when used in bandages and the like. The swab of Seifert is capable of performing the function of stopping blood flow.

17. For Claim 2, Seifert teaches that the stick is hollow (Figs. 1 and 3). The reservoir is formed by a liquid tight seal located substantially at the proximal end of the stick (see reference number 14 of Figs. 1 and 3, col. 3, lines 5-10, and col. 4, lines 58-59). Seifert teaches a liquid tight, frangible seal located in the distal portion of the stick (see reference numbers 16 and 18 of Figs. 1 and 3, col. 3, lines 5-11 and 38-42, and col. 4, lines 58-61).

18. For Claim 3, which is dependent on Claim 2, Seifert discloses the frangible seal being located substantially at the distal end of the stick. See Fig. 3. As stated above in paragraph 6, for purposes of this examination, the Examiner interprets the limitation "located substantially at the distal end of the stick" to mean that the frangible seal is located in the vicinity of the distal end.

19. For Claim 4, which is dependent on Claim 2, Seifert discloses the frangible seal being located downwardly from the distal end of the stick (see Figs. 1 and 3). The stick is hollow in the region between the frangible seal and the distal end of the stick. See

Figs. 1 and 3, col. 4, lines 35-40, and col. 5, lines 54-58. As stated above in paragraph 6, for purposes of this examination, the Examiner interprets the limitation "located downwardly from the distal end of the stick" to mean that the frangible seal is located in the vicinity of the distal end.

20. Claim 15, as best understood by the Examiner, is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,740,194 to Barabino et al.

21. Barabino discloses a swab having a stick and a reservoir for containing a liquid. (See Figs. 1 and 4, col. 3, lines 5-17, and col. 6, lines 9-13.) The swab has an element for applying a liquid and a hemostatic element (both reference numbers 66 of Fig. 4). The cotton form of Barabino is a hemostatic element, for the same reasons as described above in paragraph 11. The element for applying a liquid and the hemostatic element are secured to opposite ends of the stick (see Fig. 4). The reservoir is in fluid communication with the element for applying a liquid (see Figs. 1 and 4 and col. 3, lines 5-17).

22. Thus, Heimlich reasonably appears to teach and disclose every element of Claims 1, 5, 6, 10, and 13-14. Seifert reasonably appears to teach and disclose every element of Claims 1-4. Barabino reasonably appears to teach and disclose every element of Claim 15.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. Claims 7-9, as best understood by the Examiner, are rejected under 35 U.S.C.

103(a) as being unpatentable over U.S. Patent No. 3,324,855 to Heimlich in view of

U.S. Patent No. 3,343,540 to Siegel. For Claim 7, Heimlich discloses a swab that may

be used for wound cleansing (see Figs. 1 and 4 and col. 2, lines 65-68). Heimlich

teaches the swab having a stick (reference number 10 of Figs. 1 and 4, and col. 2, line

66) and a wound treating element (reference number 18 of Figs. 1 and 4, and col. 3,

lines 24-30). The stick has a proximal portion, a proximal end, a distal portion, and a

distal end (see Fig. 4). The stick has a reservoir for containing a liquid (reference

number 52 of Fig. 4, and col. 6, lines 3-8). The wound treating element is secured to

the distal portion (see Fig. 4). The wound treating element includes a cleansing

element, which is also a hemostatic element for effecting hemostasis of a wound

(reference number 18 of Fig. 4). The swab may be made of gauze (see Heimlich, col.

3, lines 24-33), which is known for a hemostatic effect. The reservoir is in fluid

communication with the cleansing element (Fig. 4 and col. 6, lines 12-16). Heimlich

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discloses the hemostatic element including a substrate material of sponge, gauze, or foam (see col. 3, lines 24-34).

26. Heimlich does not disclose the hemostatic element comprising a substrate material and an additional hemostatic agent. Siegel discloses a hemostatic swab made of a stick and a hemostatic element. The hemostatic element has a substrate material of an absorbent wad of cotton or the like (col. 1, lines 41-47 and 61-64). A hemostatic (styptic) agent such as alum is impregnated on the absorbent wad. See col. 1, lines 61-64, and col. 2, lines 69-71. Siegel teaches dipping an absorbent wad (such as the gauze of Heimlich) into a liquid mixture, which may be a styptic agent, to impregnate the wad (see col. 1, lines 48-64). It would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to modify the hemostatic substrate of Heimlich to include an additional hemostatic agent, to improve convenience.

27. For Claim 8, which is dependent on Claim 7, Heimlich and Siegel teach a swab having a stick, a wound treating element, a reservoir, a cleansing element, and a hemostatic element having a substrate material and a hemostatic agent, as described above in paragraphs 26-27. Heimlich also teaches the substrate material being of gauze, sponge, or foam, as stated above in paragraph 26. For Claim 9, which is dependent on Claim 8, Heimlich teaches the substrate material being of foam (see col. 3, lines 24-34).

28. Claim 11 (which is dependent on Claim 10), as best understood by the Examiner, is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No.

3,324,855 to Heimlich in view of U.S. Patent No. 2,688,586 to Eberl et al. Heimlich

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discloses a swab having a stick and a wound treating element, as discussed in paragraph 26. The stick has a reservoir for containing a liquid. The wound treating element is secured to the distal portion and includes a cleansing element, which is also a hemostatic element. The reservoir is in fluid communication with the cleansing element.

29. Heimlich does not disclose the hemostatic element being an alginate salt. Eberl teaches hemostatic alginate salt compositions, which may be coated onto the surface of gauze in surgical dressings. (See Eberl, col. 2, lines 41-55.) Eberl teaches that alginate salt compositions are more effective in hemostasis than other hemostatic compositions (see col. 2, lines 14-55). It would have been obvious to modify the hemostatic element of Heimlich to include alginate salt compositions, to increase the hemostatic effect.

30. Claim 12, which is dependent on Claim 10, is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,324,855 to Heimlich in view of U.S. Patent No. 2,423,707 to Kenyon et al. Heimlich teaches the swab having a stick (reference number 10 of Figs. 1 and 4, and col. 2, line 66) and a wound treating element (reference number 18 of Figs. 1 and 4, and col. 3, lines 24-30). The stick has a reservoir for containing a liquid (reference number 52 of Fig. 4, and col. 6, lines 3-8). The wound treating element is secured to the distal portion (see Fig. 4). The wound treating element includes a cleansing element, which is also a hemostatic element for effecting hemostasis of a wound (reference number 18 of Fig. 4). The swab may be made of gauze (see Heimlich, col. 3, lines 24-33), which is known for a hemostatic effect. The

reservoir is in fluid communication with the cleansing element (Fig. 4 and col. 6, lines 12-16).

31. Heimlich does not disclose the hemostatic element being oxidized cellulose fiber. Kenyon discloses a hemostatic element including fabric or gauze of oxidized cellulose fibers. See Kenyon, col. 1, lines 1-2 and 50-55. Kenyon states that "it is customary to use a cotton sponge or gauze packing to aid in checking the flow of blood" and describes oxidation as imparting a "very marked hemostatic effect" to the cotton or other cellulose. See Kenyon, col. 1, lines 12-15 and 42-52. It would have been obvious to modify the hemostatic element of Heimlich to include oxidized cellulose fiber, to increase the hemostatic effect.

Conclusion

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,827,307 to Tipton shows a disposable curette with a wound scraping implement at one end and a swab at the other, the swab being in fluid communication with a crushable ampule containing a hemostatic solution. U.S. Patent Nos. 4,390,519 to Sawyer and 4,404,970 to Sawyer show hemostatic bandages and pads. U.S. Patent No. 3,327,706 to Watson, Sr. and Patent Publication US 2004/0138606 A1 show disposable hemostatic swab products. U.S. Patent No. 2,800,673 to Lazisky shows a two-sided applicator. U.S. Patent No. 6,283,933 to D'Alessio et al. shows an applicator with a drying swab at one end, and an applicator swab in fluid communication with a frangible vial at the other. U.S. Patent No. 4,173,978 to Brown, 4,225,254 to Hoiberg et al., 3,891,331 to Avery, 3,876,314 to

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Nehring, and 4,206,843 to Rainey show applicator swabs. U.S. Patent Nos. 4,730,949 to Wilson and 5,009,652 to Morgan et al. show two-sided medical scrubbers. Patent Publication US 2001/0031221 A1 shows a hemostatic device with a cleaning fluid flow. U.S. Patent No. 4,551,100 to Fischer and Patent Publication US 2002/0169476 A1 show hemostatic methods.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry I. Schwartz can be reached on (571)272-4390. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

35. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PLC

Paula L Craig
Examiner
Art Unit 3761



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